



Introduction to Risk Assessment



Introduction to Risk Assessment

What is Risk ?

EPA considers risk to be the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor.





What is Risk Assessment?

A Consistent process for estimating & documenting public health & ecological threats.



Objectives of a Risk Assessment

- Help determine the need for action
- Provide a basis for defining contaminant levels that are protective of public health
- Provide a basis for evaluating remedial decisions
- Process for evaluating and documenting public health threats



A Risk Assessment **IS NOT**:

- A study of existing health conditions you may already have
- A medical examination
- A re-creation of ways you might have been exposed to contaminants in the past from industrial/environmental exposures to current environmental exposures
- A study that will tell you whether any existing health problems you have were caused by past contact you may have had with Libby amphibole

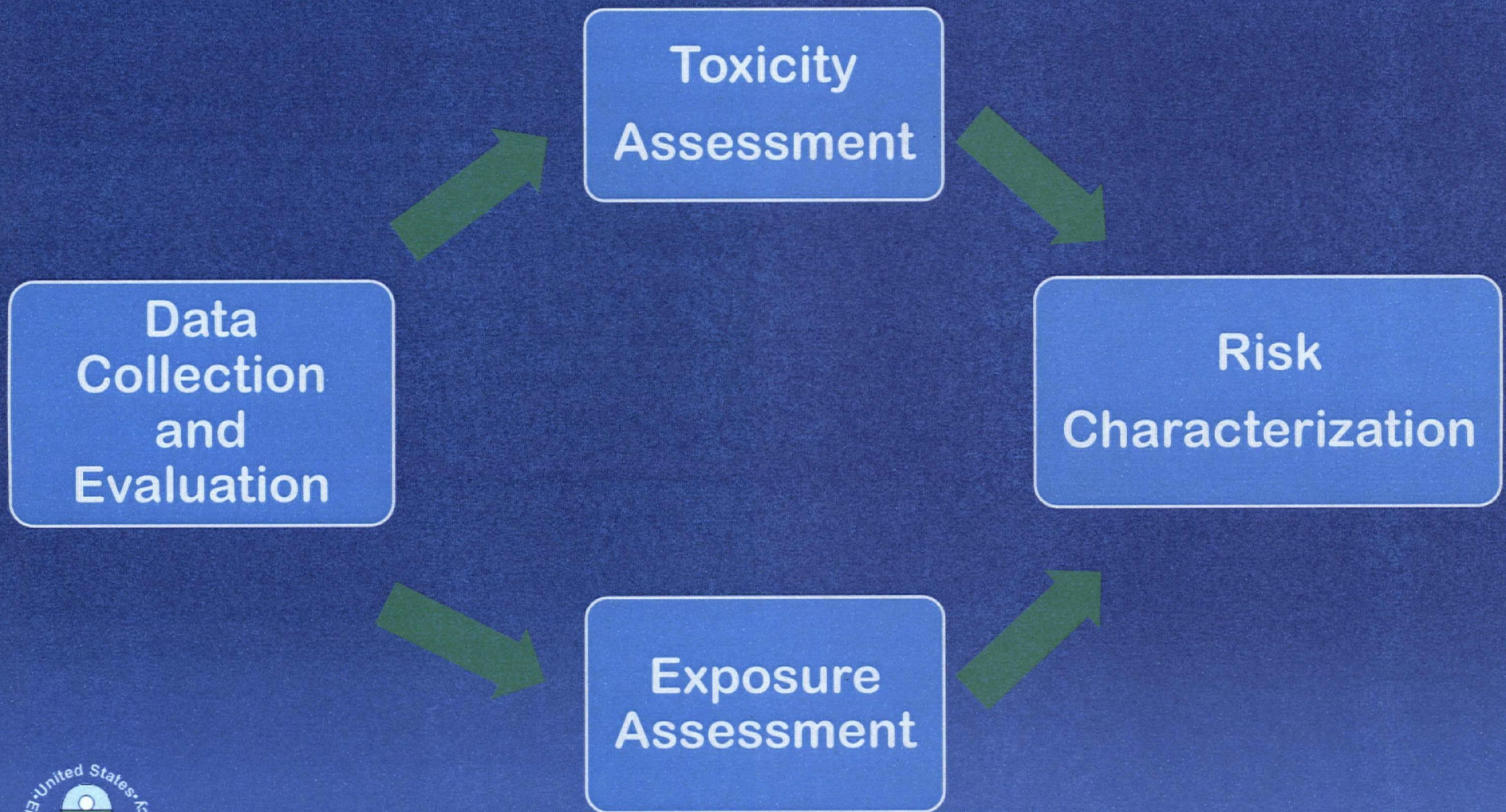


A Risk Assessment IS:

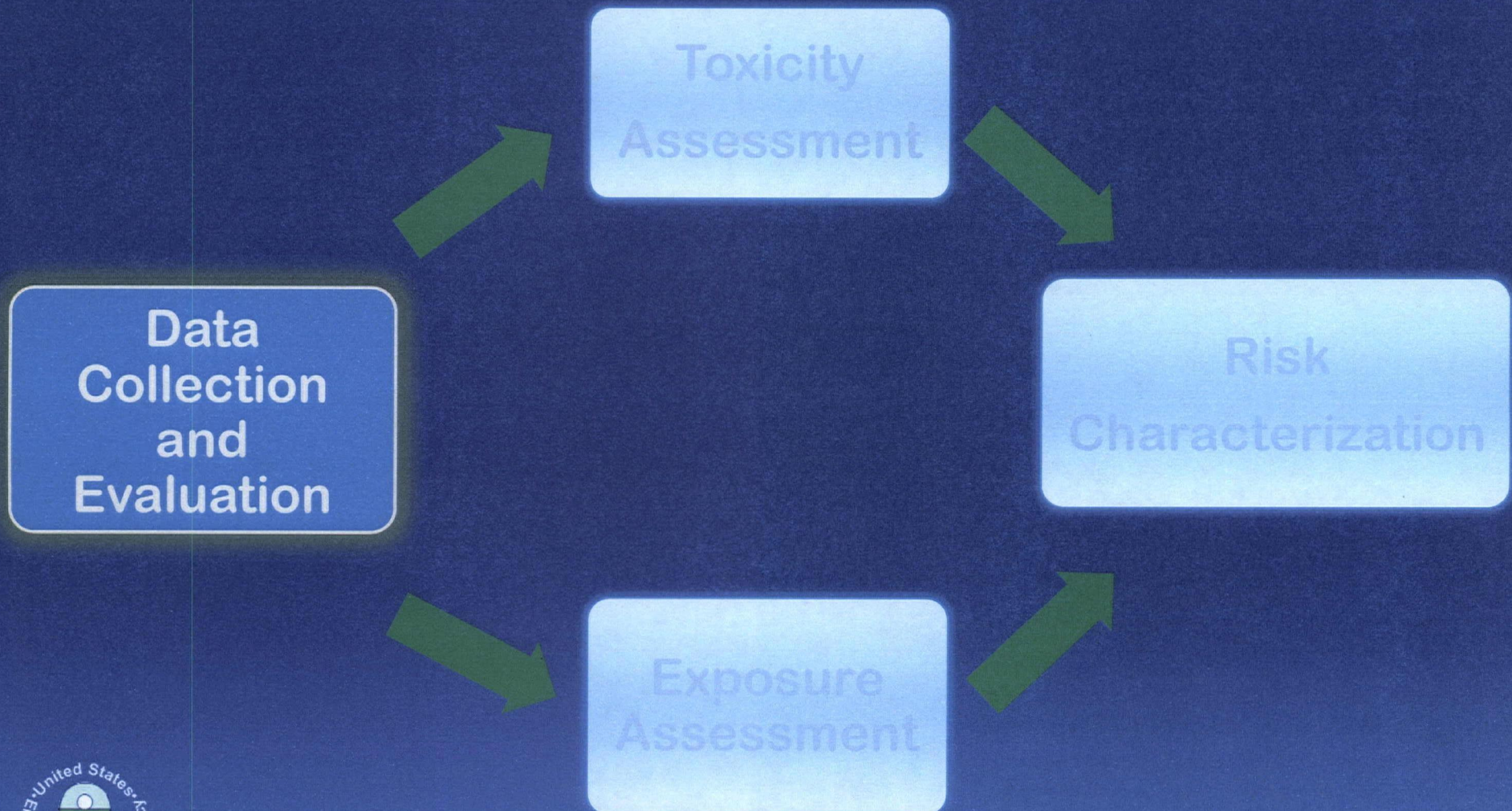
- A comprehensive study resulting in estimates of the various ways people might come in contact with Libby amphibole [inhalation]
- An estimate of how likely it is that adverse human health effects might occur because of exposure to Libby amphibole.
- A tool to assist EPA in making cleanup decisions



Four Steps of Risk Assessment



Four Steps of Risk Assessment

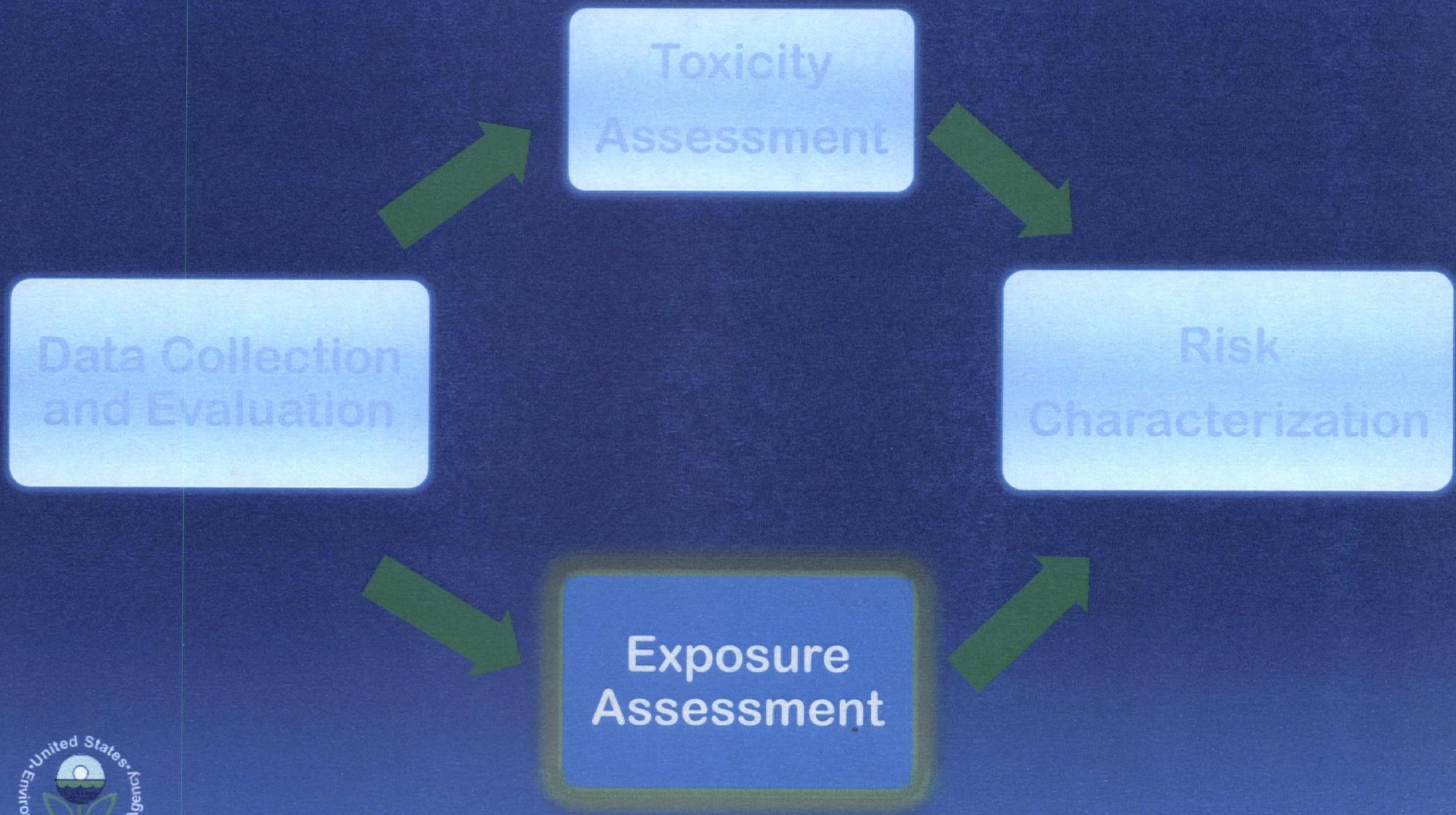


Data Collection and Evaluation

- Public Input
- Sampling Plan
 - Soil Sampling
 - Activity-based Sampling
- Site Investigation
 - Attics
 - Schools
 - Yards
 - Commercial and public properties
- Data Evaluation



Four Steps of Risk Assessment

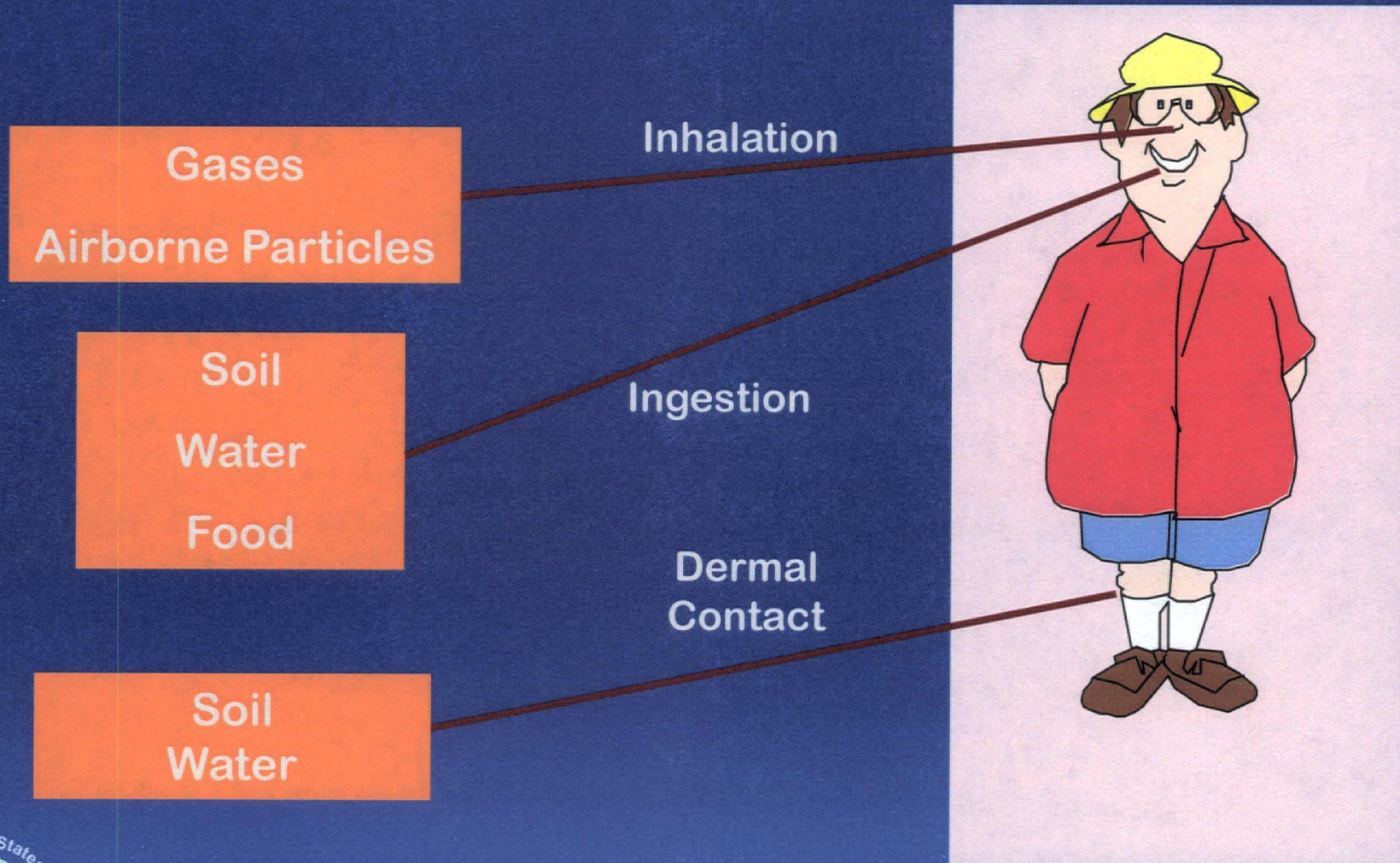


What is an Exposure Assessment ?

The estimation of the magnitude, frequency, duration and route of exposure.



What is an Exposure Route?



A Completed Exposure Pathway

All four elements are required:

- A source & mechanism of chemical release
- A transport medium
- A point of human contact/exposure
- An exposure route at the contact point



Estimating Exposure

- Use concentration of contaminant in media (fibers in air) and exposure estimates to calculate dose for each chemical
- Add all exposures via all pathways



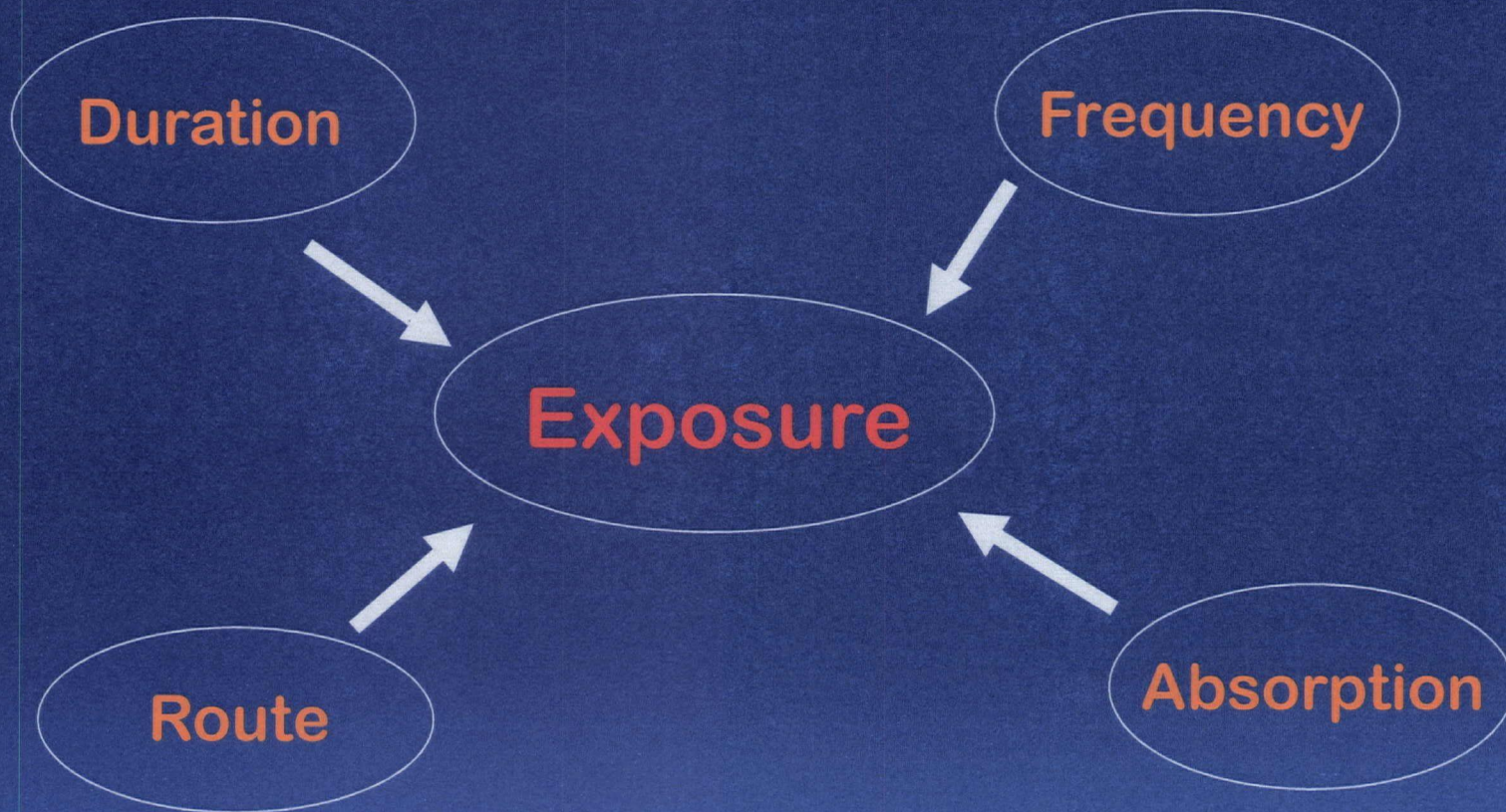
How Do We Calculate Chemical Intake (Exposure)?

Environmental
Concentration

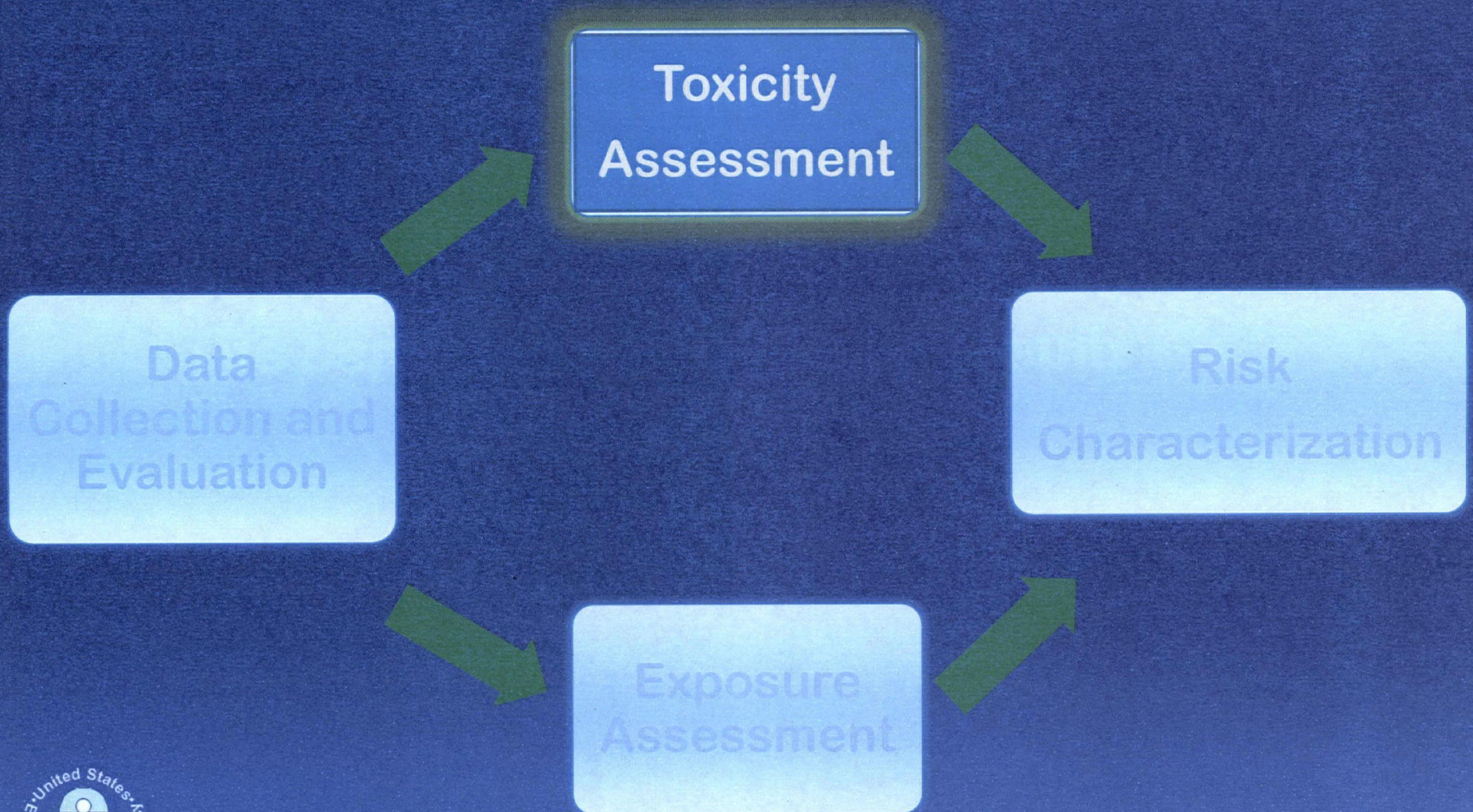
X

Exposure Estimates
that Describe
Exposed Population

Exposure Assessment Uncertainties



Four Steps of Risk Assessment



What is a Toxicity Assessment ?

The estimation of the relationship between dose of a substance and the biological response.



Some Basic Toxicological Concepts

Two categories of toxic chemicals:

- **Noncarcinogenic Chemicals**

Believed to act via a “threshold” mechanism of action. This means that there is a level of exposure (i.e., a threshold) below which it is unlikely to have an effect.

- **Carcinogenic Chemicals**

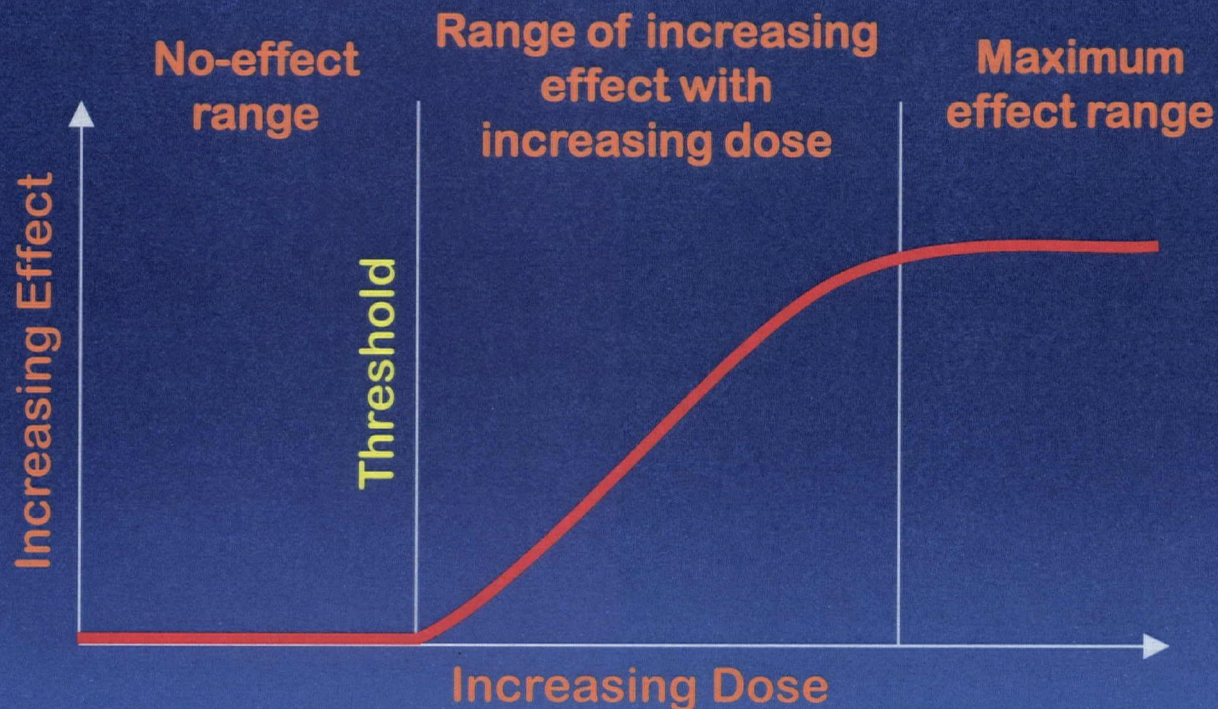
Believed to act via a “non-threshold” mechanism of action. There is a risk associated with any exposure level.



Threshold Response

[Non Cancer Effects]

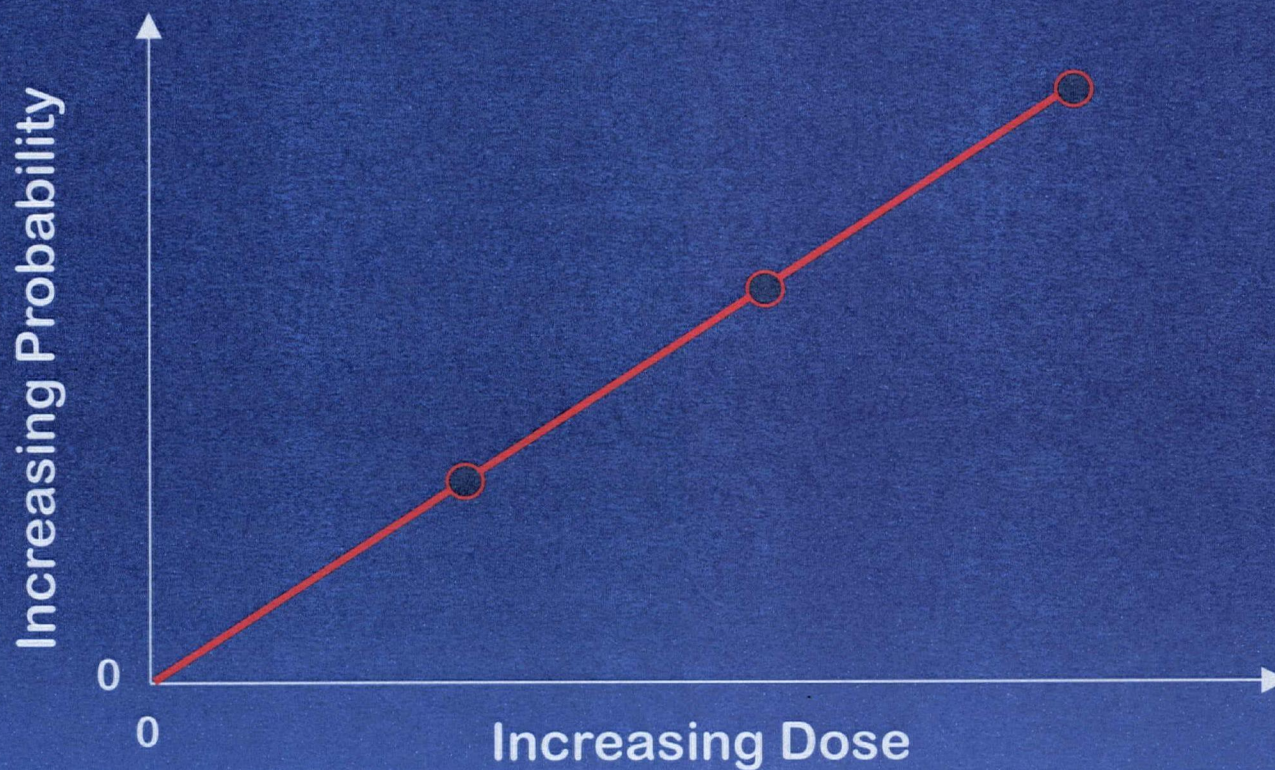
Below some dose (**threshold**) an adverse response (or some specific effect) is not expected.



Non-Threshold Response

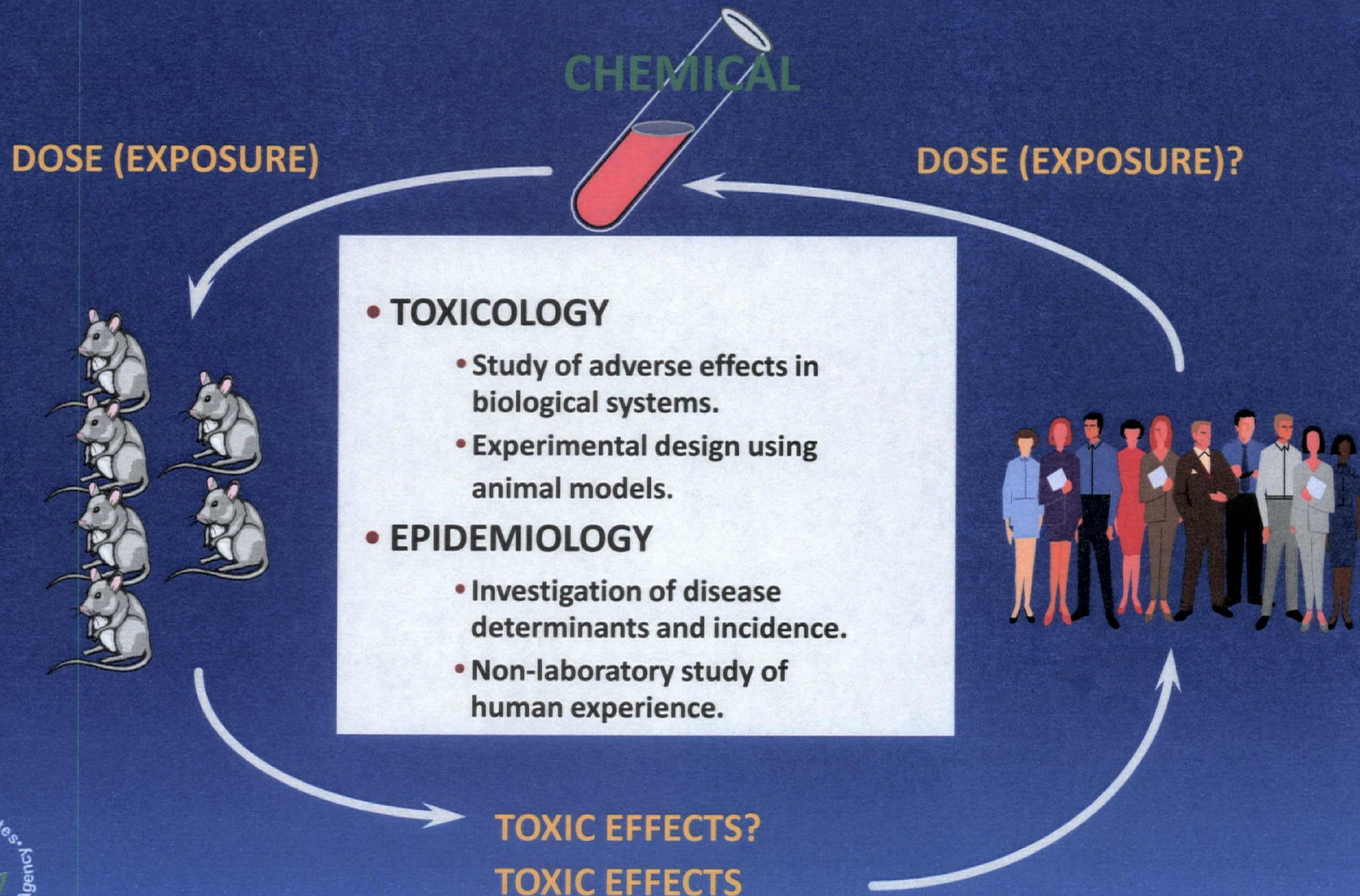
[Cancers Effects]

Some probability of effect at any dose.

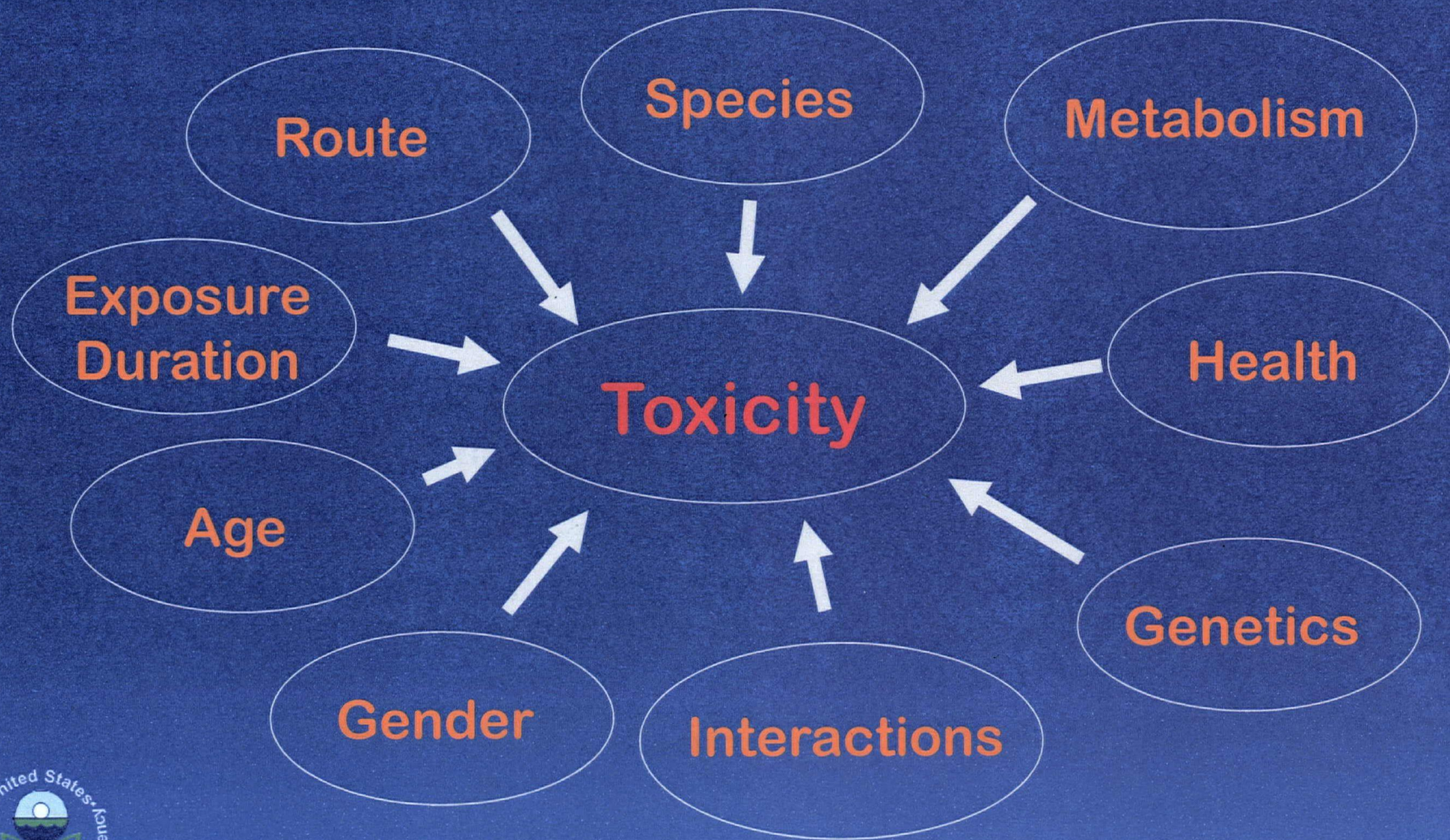


Toxicology and Epidemiology

Of men or mice?



Toxicity Assessment Uncertainties



Animal Toxicology Studies



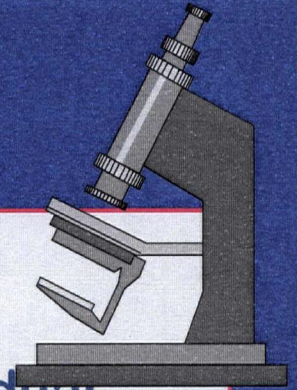
Promise

- Readily manipulated exposure conditions
- Ability to measure many types of responses
- Ability to assess effect of host characteristics and other modifiers of response
- Potential to evaluate mechanisms

Problems

- Uncertainties in relevance of animal response to human response
- Controlled housing, diet, etc., of questionable relevance to humans
- Exposure concentrations and time frame often very different from those experienced by humans

Epidemiology



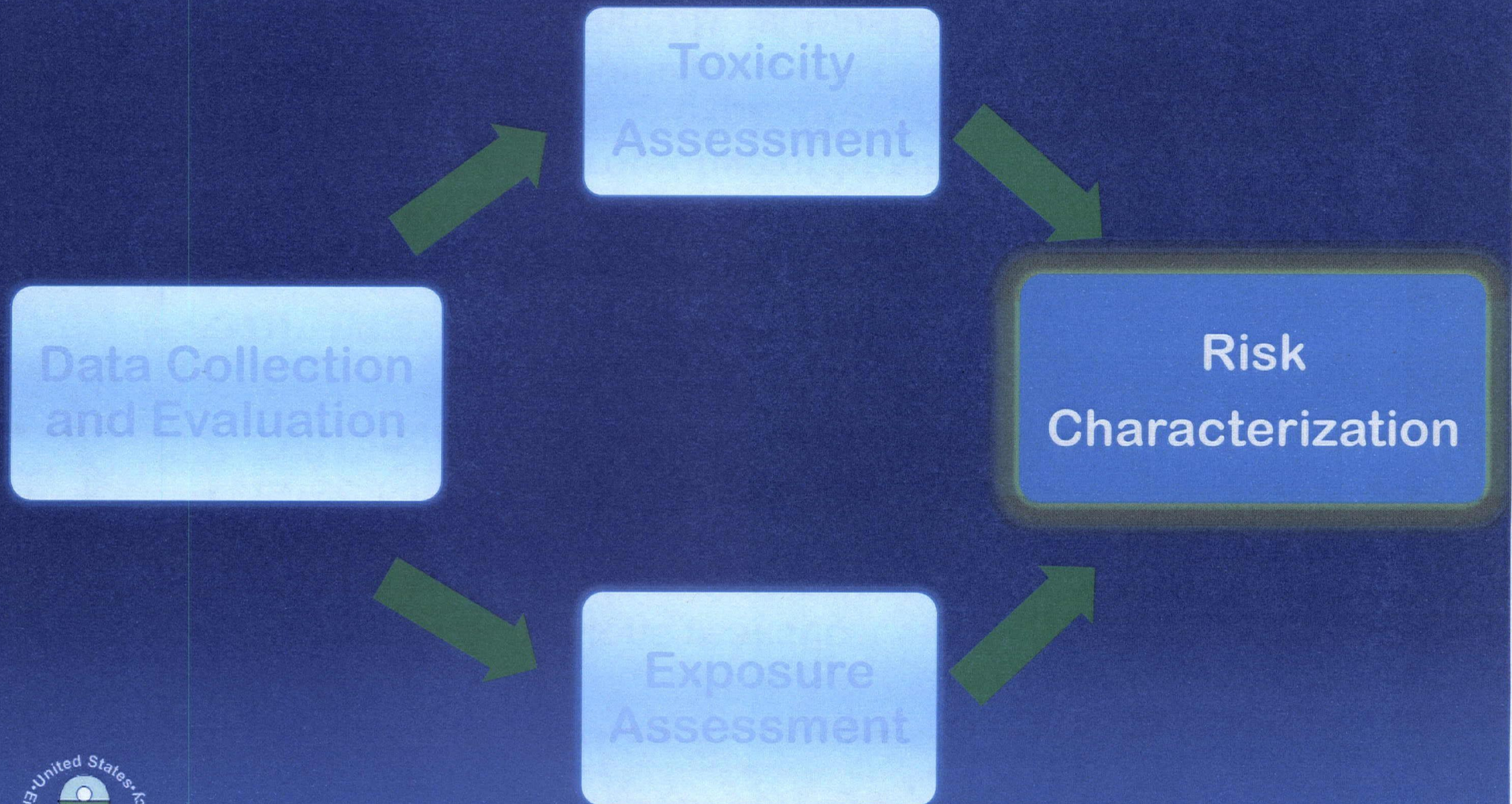
Promise

- Exposure conditions realistic
- Occurrence of interactive effects among individual chemicals
- Effects measured in humans
- Full range in human susceptibility frequently expressed

Problems

- Costly and time consuming
- Can't plan exposure
- *post facto*, not protective of health
- Difficulty in defining exposure, problems with confounding exposure
- Increase in risk must be at least 2X to be detected
- Effects measured often relatively crude (morbidity, mortality)

Four Steps of Risk Assessment



What is Risk Characterization ?

The toxicity and exposure estimates are combined into an expression of cancer risk or noncancer hazard.



How Do We Calculate Cancer Risk and Noncancer Hazard?

$$\text{Cancer Risk} = \text{Air Conc.} \times \text{IUR}^*$$

$$\text{Noncancer Hazard} = \frac{\text{Air Conc.}}{\text{RfC}^\#}$$



*IUR = Inhalation Unit Risk

^\#RfC = Reference Concentration

What might a cumulative risk assessment look like for Libby?

An example of how the pieces fit together for age range 6 to 11 years

- Exposure Point Concentrations (EPCs) for each activity
 - Walking in town
 - Playing in the athletic field
 - Attending school
 - Bicycling in town
 - Riding in motor vehicle
 - Quiet/Resting activities
- Time Weighted Fractions (TWFs) for each activity
 - Walking in town: 1 hr/day x 365 days/yr
 - Playing in the athletic field: 3 hr/day x 365 day/yr
 - Attending school: 6 hr/day x 180 day/yr
 - Bicycling in town: 3 hr/day x 365 day/year
 - Riding in motor vehicle: 1 hr/day x 365 days/year
 - Quiet/Resting activities (remainder of day)



What might a cumulative risk assessment look like for Libby?

How the pieces may fit together for an adult:

Activity	EPC	Hr/day	Days/yr	Duration[Yr]	IUR	Risk by Activity
Sleeping/resting		12	350	70		
House work		2	50	50		
Gardening		3	14	30		
Bicycling		3	26	30		
Walking		4	40	65		
Shopping		3	50	50		
Driving		1	350	50		
Mowing Lawn		2	26	50		
Sedentary Occupation		8	250	25		

Total Risk

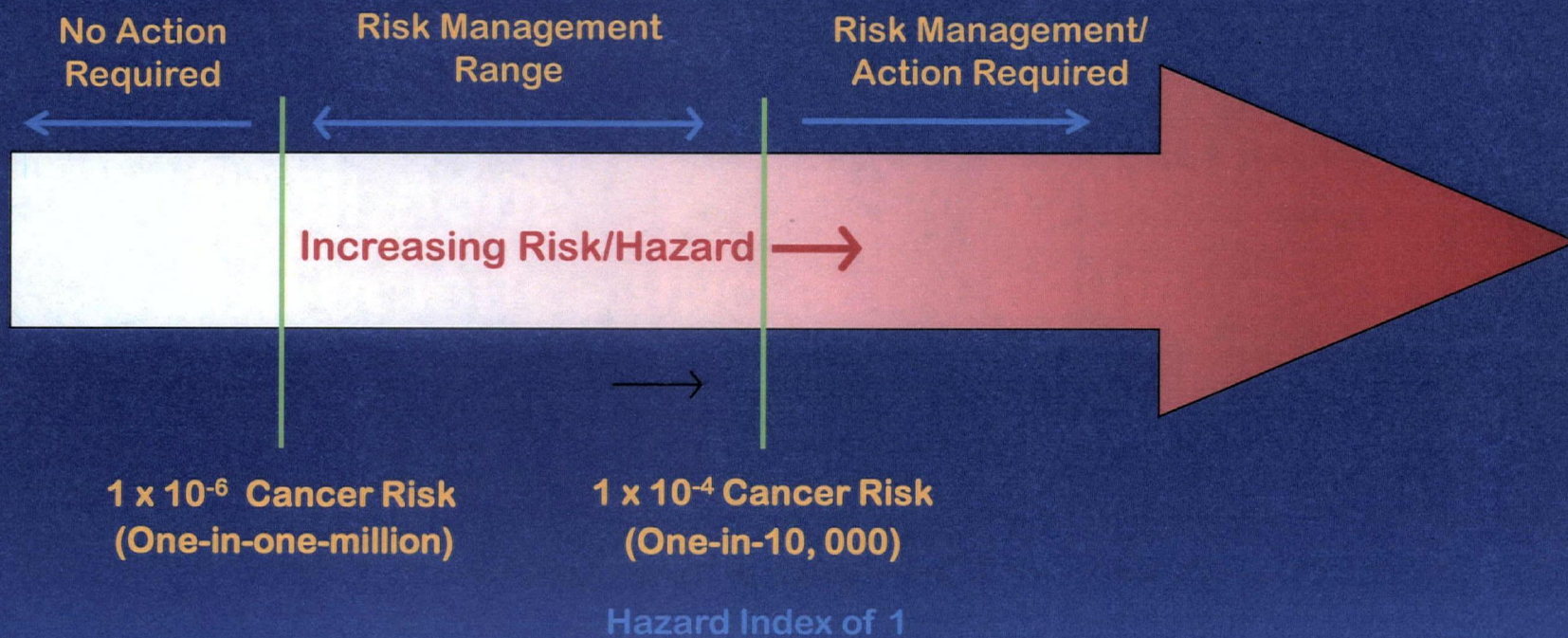


Risk Assessment versus Risk Management

- Risk Assessment - Estimates risk using science and science policy assumptions.
- Risk Management - Manages the risk by taking into account technological, social, economic and scientific considerations.



Risk Assessment/Risk Management Interface



Risk Management

The Nine Criteria

- Protection of Human Health & Environment
- Regulatory mandates
- Long-term effectiveness
- Reduction of toxicity, mobility, or volume
- Short-term effectiveness
- Implementability
- Cost
- State acceptance
- Community acceptance



Questions ?